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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,393	10/26/2001	Joel S. Hochman	Athenal	9804

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT      PAPER NUMBER

3736

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/007,393	Applicant(s) HOCHMAN ET AL.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on \_\_\_\_\_.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-15 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-15 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 26 October 2001 is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
  - 1.  Certified copies of the priority documents have been received.
  - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed October 26, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copy of the prior art reference cited under Non Patent Literature Documents has been provided. As such, that reference has not been considered. The U.S. Patent Documents cited in said information disclosure statement have been considered.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "38" as illustrated in Figures 5 and 6. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the

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following is required: the specification does not disclose that the probe is "inserted 'in-situ' into the vaginal vault" as claimed in claim 6.

***Claim Objections***

4. Claim 2 is objected to because of the following informalities: in line 2, "wireless" apparently should be deleted from the limitation in order to maintain consistent terminology with its antecedent. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitations "the one hand" in line 13 and "the other hand" in line 14. There is insufficient antecedent basis for these limitations in the claim. There are no hands recited in the claim prior to these recitations, and it is unclear how the hands relate to the claimed method.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 6 recites that the sealed unit is inserted “in-situ” into the vaginal vault. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that the sealed unit is adapted to be inserted “in-situ” into the vaginal vault.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4 and 6-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Eini et al. (‘037). Eini et al. teach a system **50** including an intravaginal device **10** for electrically stimulating and for sensing electrical activity of muscles and nerves defining the intravaginal cavity. The device includes a separate, portable, non-implanted, intravaginally containable combination probe **10** and transceiver **20** that is provided with means for sensing vaginal

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conditions and stimulating perineal musculature and nerves. The combination probe and transceiver is provided with 2-way wireless communication means **26/28** for transmitting information that is transduced and for receiving control and programming signals. The system **50** further includes a separate combination controller **52** and transceiver that is provided with wireless means **54/58** for sending signals to the probe and for receiving signals therefrom. A wireless signal feedback loop is provided between the controller and the probe. The controller **52** includes means for wirelessly altering operation settings of the probe. The probe is a sealed unit that is provided with means for transducing changes in the vaginal environment in the form of a muscle contraction sensors and stimulators **24**. The controller can be a hand-held unit that can wirelessly alter stimulation signal levels at the probe. The stimulators on the probe include means for automatic adjustment of stimulation levels in response to sensed muscle contractions and changes in the vaginal environment and can be programmed to provide increasing stimulation over a given period of time. The controller and probe transmit signals to and/or receive signals from external devices **56**, such as a personal computer. In operation, the probe is inserted intravaginally such that the probe senses vaginal conditions and stimulates perineal musculature and nerves. The separate controller then uses 2-way wireless communication means to send signals to the probe and to receive signals therefrom such that a wireless signal feedback loop is provided between the probe and the controller.

11. Claims 1, 2, 4-6, 11, 12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Frohn ('254). Frohn teaches a system including a device for monitoring periods of ovulation. The device includes a separate, portable, non-implanted, intravaginally

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containable combination probe 11 and transceiver 19 that is provided with means for sensing vaginal conditions. The combination probe and transceiver is provided with 2-way wireless communication means 19 for transmitting information that is transduced and for receiving control and programming signals. The system further includes a separate combination controller (col. 3, lines 60-68) and transceiver that is provided with wireless means for sending signals to the probe and for receiving signals therefrom. A wireless signal feedback loop is provided between the controller and the probe. The controller includes means for wirelessly altering operation settings of the probe. The probe 11 is a sealed unit that is provided with means for transducing changes in the vaginal environment, particularly changes related to temperature, in the form of temperature transducing sensors 16. The controller and probe transmit signals to and/or receive signals from external devices, such as a personal computer. In operation, the probe is inserted intravaginally such that the probe senses vaginal conditions. The separate controller then uses 2-way wireless communication means to send signals to the probe and to receive signals therefrom such that a wireless signal feedback loop is provided between the probe and the controller.

### ***Conclusion***


12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guice et al. ('390) teach a system and method for monitoring the health and status of livestock. Kobozev ('199) teaches an electrical gastro-intestinal tract stimulator.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
Charles A. Marmor, II  
Primary Examiner  
Art Unit 3736

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September 17, 2003